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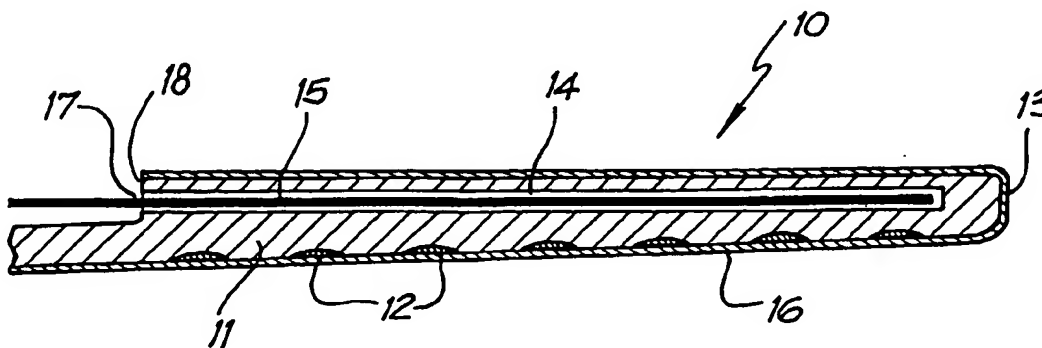
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(54) Title: INSERTION TOOL FOR A COCHLEAR IMPLANT ELECTRODE ARRAY



(57) Abstract: A cochlear implant electrode assembly device (10) comprising an elongate electrode carrier member (11), and a shape element (15) formed of a memory material, such as Nitinol. The elongate member (11) is made of a resiliently flexible first material and has a length and a plurality of electrodes (12) mounted thereon adapted to apply a preselected tissue stimulation. The elongate member (11) has a pre-formed curved orientation that at least substantially matches an inside surface of a cochlea, an implantable orientation different to said pre-formed orientation that allows said member to be inserted into an implantee's cochlea, and an at least one intermediate orientation between said implantable orientation and said pre-formed orientation. The shape element (15) is removably positioned within the elongate member (11) and extends along at least a portion of the length thereof. The shape element (15) has a first shape selected for biasing the elongate member (11) into the implantable orientation when the shape element is at a first temperature, and at least a second shape that allows the elongate member (11) to adopt said at least one intermediate orientation when the shape element (15) is exposed to a temperature of the cochlea (30) being different than the first temperature.

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"Insertion tool for a cochlear implant electrode array"

Field of the Invention

The present invention relates to an implantable device and, in particular, to an implantable cochlear electrode assembly.

5 Background of the Invention

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these types, conductive hearing loss occurs where the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the
10 ossicles. Conductive hearing loss may often be helped by use of conventional hearing aid systems, which amplify sound so that acoustic information does reach the cochlea and the hair cells.

In many people who are profoundly deaf, however, the reason for deafness is sensorineural hearing loss. This type of hearing loss is due to the
15 absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

20 It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve. US Patent 4532930, the
25 contents of which are incorporated herein by reference, provides a description of one type of traditional cochlear implant system.

Cochlear implant systems have typically consisted of two key components, namely an external component commonly referred to as a processor unit, and an implanted internal component commonly referred to
30 as a stimulator/receiver unit. Traditionally, both of these components have cooperated together to provide the sound sensation to an implantee.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds and particularly speech into a
35 coded signal, a power source such as a battery, and an external antenna transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted stimulator/receiver unit situated within a recess of the temporal bone of the implantee. This transcutaneous transmission occurs through use of an inductive coupling provided between
5 the external antenna transmitter coil which is positioned to communicate with an implanted antenna receiver coil provided with the stimulator/receiver unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted stimulator/receiver unit. Conventionally, this link
10 has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted stimulator/receiver unit typically included the antenna receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and
15 outputs a stimulation signal to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The external componentry of the cochlear implant has been traditionally carried on the body of the implantee, such as in a pocket of the
20 implantee's clothing, a belt pouch or in a harness, while the microphone has been mounted on a clip mounted behind the ear or on a clothing lapel of the implantee.

More recently, due in the main to improvements in technology, the physical dimensions of the speech processor have been able to be reduced
25 allowing for the external componentry to be housed in a small unit capable of being worn behind the ear of the implantee. This unit has allowed the microphone, power unit and the speech processor to be housed in a single unit capable of being discretely worn behind the ear, with the external transmitter coil still positioned on the side of the user's head to allow for the
30 transmission of the coded sound signal from the speech processor and power to the implanted stimulator unit.

Together with improvements in available technology much research has been undertaken in the area of understanding the way sound is naturally processed by the human auditory system. With such an increased
35 understanding of how the cochlea naturally processes sounds of varying frequency and magnitude, there is a need to provide an improved cochlear

implant system that delivers electrical stimulation to the auditory nerve in a way that takes into account the natural characteristics of the cochlea.

It is known in the art that the cochlea is tonotopically mapped. In other words, the cochlea can be partitioned into regions, with each region
5 being responsive to signals in a particular frequency range. This property of the cochlea is exploited by providing the electrode assembly with an array of electrodes, each electrode being arranged and constructed to deliver a cochlea stimulating signal within a preselected frequency range to the appropriate cochlea region. The electrical currents and electric fields from each electrode
10 stimulate the cilia disposed on the modiola of the cochlea. Several electrodes may be active simultaneously.

It has been found that in order for these electrodes to be effective, the magnitude of the currents flowing from these electrodes and the intensity of the corresponding electric fields, are a function of the distance between the
15 electrodes and the modiola. If this distance is relatively great, the threshold current magnitude must be larger than if the distance is relatively small. Moreover, the current from each electrode may flow in all directions, and the electrical fields corresponding to adjacent electrodes may overlap, thereby causing cross-electrode interference. In order to reduce the threshold
20 stimulation amplitude and to eliminate cross-electrode interference, it is advisable to keep the distance between the electrode array and the modiola as small as possible. This is best accomplished by providing the electrode array in the shape which generally follows the shape of the modiola. Also, this way the delivery of the electrical stimulation to the auditory nerve is most
25 effective as the electrode contacts are as close to the auditory nerves that are particularly responsive to selected pitches of sound waves.

In order to achieve this electrode array position close to the inside wall of the cochlea, the electrode needs to be designed in such a way that it assumes this position upon or immediately following insertion into the
30 cochlea. This is a challenge as the array needs to be shaped such that it assumes a curved shape to conform with the shape of the modiola and must also be shaped such that the insertion process causes minimal trauma to the sensitive structures of the cochlea. In this sense it has been found to be desirable for the electrode array be generally straight during the insertion
35 procedure.

Several procedures have been adopted to provide an electrode assembly that is relatively straightforward to insert while adopting a curved configuration following insertion in the cochlea. In one case, a platinum wire stylet is used to hold a pre-curved electrode array in a generally straight configuration up until insertion. Following insertion, the platinum stylet is withdrawn allowing the array to return to its pre-curved configuration.

In another development, a bimetallic filament (such as nickel/titanium) or a filament made of a nickel/titanium alloy is positioned in the electrode assembly and used to again hold a pre-curved electrode array in a generally straight configuration while the array is at about room temperature. On insertion into the body and exposure to body temperature, the filament bends into a pre-selected curved configuration.

In a still further arrangement, a longitudinal element that is arranged on one side of the array and constructed to change its dimension on insertion can be utilised. For example, the longitudinal element could include a hydrogel such as polyacrylic acid (PAA) which expands after insertion by absorbing water from the cochlear fluid.

In developing such electrode array designs, it is of great importance that the design be constructed to minimise potential damage to sensitive structures in the cochlear on insertion and placement. Each of the above constructions suffer from a number of disadvantages in this regard.

Still further, it has been proposed to straighten pre-curved electrode arrays using inserted longitudinal elements or surrounding sheaths formed from bioresorbable materials that dissolve or soften on implantation. A disadvantage with use of such bioresorbable materials is that, due to the generally wet nature of the surgical environment, the polymer can dissolve or soften before the electrode array is appropriately positioned.

US Patent 6119044 provides a description of another arrangement adapted to ensure electrode contacts of an implantable array are against the modiolar wall of the cochlea following implantation. In this arrangement, a positioning wire made from memory wire is positioned in a longitudinal channel of the array. On insertion into the cochlea and exposure to body temperature, the positioning wire is adapted to adopt a curved spiral shape which causes the electrode contacts to be forced against the modiolar wall.

In this arrangement, the positioning wire serves to maintain the electrode array in its spiral configuration following implantation and provides

a permanent bending force to the electrode array to ensure that the spiral configuration is adopted. A disadvantage of this arrangement is that should for any reason the array require replacement or removal, such an arrangement would be difficult to remove without causing damage to the delicate
5 structures of the cochlea.

The present invention is directed to an electrode assembly adapted to overcome some of the difficulties of prior art electrode assemblies.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the
10 purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

15 Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements,
20 integers or steps.

According to a first aspect, the present invention is an implantable tissue-stimulating device comprising:

an elongate member made of a resiliently flexible first material and having a length and a plurality of electrodes mounted thereon adapted to
25 apply a preselected tissue stimulation, the elongate member having a pre-formed orientation, an implantable orientation different to said pre-formed orientation that allows said member to be inserted into an implantee's body, and an at least one intermediate orientation between said implantable and said pre-formed orientation; and
30 a shape element removably positioned within the elongate member and extending along at least a portion of the length thereof, said element having:
a first shape selected for biasing said elongate member into said implantable orientation when the shape element is at a first temperature; and
at least a second shape that allows the elongate member to adopt
35 said at least one intermediate orientation when the shape element is exposed to a pre-determined temperature different than said first temperature.

In a preferred embodiment of this aspect, the pre-formed orientation of the elongate member is curved. More preferably, the elongate member adopts a spiral curvature when in the pre-formed orientation.

According to a second aspect, the present invention is a cochlear
5 implant electrode assembly device comprising:
an elongate electrode carrier member made of a resiliently flexible first material and having a length and a plurality of electrodes mounted thereon adapted to apply a preselected tissue stimulation, the elongate member having a pre-formed curved orientation that at least substantially matches an
10 inside surface of a cochlea, an implantable orientation different to said pre-formed orientation that allows said member to be inserted into an implantee's cochlea, and an at least one intermediate orientation between said implantable orientation and said pre-formed orientation; and

a shape element removably positioned within the elongate member and
15 extending along at least a portion of the length thereof, said element having:
a first shape selected for biasing said elongate member into said implantable orientation when the shape element is at a first temperature; and
at least a second shape that allows the elongate member to adopt
said at least one intermediate orientation when the shape element is exposed
20 to a temperature of the cochlea being different than said first temperature.

In this invention, the shape element biases the elongate member in the implantable orientation and serves to prevent the elongate member adopting its preferred pre-formed orientation, such as the pre-formed curved orientation defined in the second aspect. This is in contrast to the situation
25 described in US 6119044 where the positioning wire is adapted to control the orientation of the flexible carrier in all orientations.

In a preferred embodiment of each aspect, the shape element is formed from a shape memory material. The shape memory material is preferably relatively stiffer than the first material. In one embodiment, the shape
30 memory material can be a nickel-titanium alloy or Nitinol. In another embodiment, the shape memory material can be a plastics material or made from another non-metal shape memory material. In a preferred embodiment, the shape memory material of the shape element is used to hold the elongate member of the electrode array in a generally straight orientation while the
35 array is at about room temperature or at least a temperature different to body temperature (about 37°C). On insertion into the body and exposure to body

temperature, the shape element adopts the second shape. In one embodiment, the second shape allows the elongate member to adopt a curved orientation in which the tip of the elongate member has adopted at least a degree of curvature.

- 5 In a preferred embodiment, the shape element is removable from the elongate member once the elongate member has adopted its said at least one intermediate orientation. On removal of the shape element, the elongate member preferably adopts its pre-formed orientation.

The elongate member is preferably preformed from a plastics material
10 with memory. The elongate member preferably has a first end that is firstly inserted into the implantee.

In a preferred embodiment, the implantable orientation is preferably substantially straight. More preferably, the implantable orientation is straight.

- 15 In a preferred embodiment, the elongate member is formed from a suitable biocompatible material. In one embodiment, the biocompatible material can be a silicone, such as a flexible silicone elastomer-Silastic. Silastic MDX 4-4210 is an example of one suitable silicone for use in the formation of the elongate member. In another embodiment, the elongate
20 member can be formed from a polyurethane or similar material.

- In a further embodiment, the elongate member can have a resiliently flexible tip member extending forwardly from the first end of the body. The tip member preferably has a distal end and a proximal end. The tip member can have a stiffness that is relatively less stiff than said stiffening element.
25 The tip member can further be formed of a material that is substantially the same or the same stiffness as the body of the elongate member. In another embodiment, the tip member can be formed of a material that is relatively less stiff than at least a portion of the elongate member. In a further embodiment, the tip member can be formed of a material that undergoes a
30 change in stiffness, preferably a decrease in stiffness, on insertion into the body, such as the cochlea.

- In a further embodiment, the stiffness of the tip member can vary along at least a portion of its length from its distal end to its proximal end. In one embodiment, the stiffness of the tip member can vary over the entire length of
35 the tip member or only a portion thereof. The stiffness can increase from the distal end to the proximal end. In one embodiment, the stiffness of the tip

member over said portion or its length can increase gradually from its distal end towards to the proximal end. The increase in stiffness can be substantially smooth or increase in a stepwise fashion.

In a further embodiment, the tip member can be formed of the same material as the body of the elongate member. In another embodiment, the tip member can be formed of a different material to that of the body of the elongate member. The tip member can be comprised of an inner relatively stiff core of material having a tapered end, with at least the tapered end being overlaid by a relatively flexible material that extends beyond the tapered end of the core material so that the tip member undergoes a gradual decrease in flexibility in the region of the tapered end of the core moving away from the distal end.

The tip member can be formed separately to the body of the elongate member and mounted thereto. For example, the tip member can be adhered to the first end of the body of the elongate member. In another embodiment, the tip member can be integrally formed with the body of the elongate member. The tip member can be formed from a silicone material. In another embodiment, the tip member can be formed of an elastomeric material, such as polyurethane.

In another embodiment, the tip member can have a plurality of metallic particles dispersed therethrough. The metallic particles can be substantially evenly dispersed through the tip member. Alternatively, the metallic particles can be non-evenly dispersed throughout the tip member. In one embodiment, the metallic particles can increase in density away from the distal end towards the proximal end of the tip member. By varying the density of the metallic particles, it is possible to vary the relative stiffness of the tip member.

The metallic particles preferably comprise a biocompatible material, such as platinum. The particles can be substantially spherical or spherical. It will be appreciated that the particles can have other suitable shapes. In one embodiment, the particles can have a diameter between about 50 μ m and 100 μ m.

In addition to, or instead of, being used to potentially modify the physical characteristics of the tip member, the provision of the metallic particles also result in the tip member being detectable by fluoroscopy and X-ray techniques. This provides another means for the surgeon to monitor the

placement and position of the tip member during or after insertion of the electrode array in the body, such as in the cochlea.

When the elongate member is in the first configuration, the tip member is preferably substantially straight and, more preferably, straight.

5 In a further embodiment, the tip member can be coated with a lubricious material. The lubricious material can be a bioresorbable or non-bioresorbable material.

The tip member can be formed from, or incorporate as a portion thereof, a bioresorbable material. The presence of the bioresorbable material
10 preferably results in the flexibility of the tip member increasing on insertion of the tip member into the body, such as the cochlea. The bioresorbable material in the tip member can be selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

15 In another embodiment, the tip member can be formed from, or incorporate as a portion thereof, a polymeric coating which becomes softer, and so increases in resilient flexibility, in the presence of moisture or body heat.

The tip member preferably has a length from its distal end to its proximal end
20 in the range of about 0.3 to 4mm, more preferably about 1.0 to 3.0 mm. The diameter of the tip member can be substantially constant for a majority of its length or can vary in diameter. The tip member can be substantially cylindrical, cylindrical, or non-cylindrical for a majority of its length. At the distal end, the diameter preferably gradually decreases to form a rounded
25 end. The maximum diameter of the tip member is preferably about 0.55mm.

In one embodiment, the tip member can be solid. In another embodiment, the tip member can have an external wall defining a cavity. In one embodiment, the cavity can have a diameter greater than that of the receiving portion of the body of the elongate member. In a further
30 embodiment, the cavity can extend from the proximal end towards the distal end of the tip member. The cavity can decrease in diameter away from the proximal end. The cavity can be in communication with a distal end of the receiving portion of the body of the elongate member. In a further embodiment, the stiffening means can extend into the cavity when positioned
35 within the device or assembly according to the respective aspects of the present invention. In a preferred embodiment, the tip member can move

relative to the stiffening means when it extends into the cavity of the tip member.

In general, the tip could be made of a combination of materials arranged in a variety of geometries depending on the specific design goal.

- 5 The outside shape and size of the tip can also be made in a variety of forms depending on the design goal.

In one embodiment, the shape element can be removably positioned in a lumen extending through the elongate member for at least a portion of its length. In one embodiment, the lumen extends through the elongate member
10 for a substantial portion of its length. In a further embodiment, the lumen extends from an opening distal the first end to or adjacent the first end. The shape element preferably extends the entire length of the lumen in the elongate member.

- The lumen can be cylindrical or have another cross-sectional shape.
15 The shape element can extend out of the opening allowing the element to be manipulated and removed from the lumen during insertion of the device.

The shape element can also be cylindrical, such as a wire, or could have another cross-sectional shape, such as oval, rectangular, triangular and others. The shape element could also be tapered along its length to achieve
20 graduation in stiffness and strength, or have other non-uniform cross-sectional shapes along its length to achieve particular desirable bending characteristics.

In a further embodiment, the elongate member can have an outer layer. The outer layer can act as a stiffening sheath for the elongate member. The
25 stiffening sheath can be formed of a bioresorbable material which dissolves or softens on exposure to a fluid. The stiffening sheath can dissolve or soften on exposure to a saline solution or a body fluid of the implantee, such as cochlear fluid.

In a further embodiment, the bioresorbable material of the stiffening
30 sheath is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is also envisaged that other suitable materials could be used.

The device can include an additional layer surrounding the stiffening sheath. The additional layer can have a first rate of fluid ingress therethrough
35 and have at least one fluid ingress means formed therein, the rate of fluid

ingress through the fluid ingress means being greater than the first rate of fluid ingress through the additional layer.

The fluid ingress means can comprise one or more openings in the additional layer. The openings can be closable. The openings can comprise
5 slits in the additional layer. The slits can be formed to allow substantially the same or the same rate of ingress of fluid through the additional layer. In another embodiment, at least one slit can allow a different rate of progress of fluid through the additional layer compared to the other slits.

The purpose of allowing the elongate member to adopt the intermediate
10 orientation, following insertion into the cochlea, is to enable the elongate member to be inserted into the cochlea in a way which minimises trauma to the walls of the cochlea. The preferred shape of this intermediate orientation is for the elongate member to assume a shape that is more curved than the straight orientation present upon insertion. By having the previously straight
15 array adopt a more curved shape, the elongate member is guided to adopt a mid-scala trajectory as it is inserted into the cochlea. This ensures that as the elongate member is carefully inserted deeper into the spiral-shaped cochlea, the intermediate curved orientation assists in ensuring that the elongate member can be inserted deep into the cochlea without causing excessive
20 trauma to the walls of the cochlea.

On subsequent removal of the shape element, the elongate member is free to adopt the fully curved pre-formed orientation desired of an implant for final position in the cochlea.

The present invention provides a surgeon with a means to at least
25 partially control the rate of curvature formation in a cochlear electrode assembly during insertion into the cochlea. Such increased control is envisaged to reduce the potential for trauma to the cochlea caused by electrode assembly insertion. The present invention also provides a means of assisting the insertion process of the electrode assembly into the cochlea by
30 allowing the electrode assembly to alter its orientation during the insertion process to allow for more desirable cochlea penetration and/or electrode positioning.

In a further embodiment, at least a portion of an outer surface of the elongate member can have a coating of a lubricious material. In one
35 embodiment, a substantial portion or the entire outer surface of the elongate member can have a coating of the lubricious material.

In this embodiment, the lubricious material can be selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials could also be used.

- 5 In a further aspect, the present invention comprises a method of implanting a tissue-stimulating device or cochlear electrode assembly device as defined herein in a body of an implantee.

In this aspect, the method can comprise a step of accessing the implantation site and then a step of inserting the device. Prior to insertion, 10 the device is preferably substantially straight or straight. On insertion, the elongate member can adopt an intermediate orientation (as defined herein). Following full insertion and after removal of the shape element, the device has preferably adopted its pre-formed orientation.

Once implanted, the electrodes can receive stimulation signals from a 15 stimulator means. The stimulator means is preferably electrically connected to the elongate member by way of an electrical lead. The lead can include the one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to 20 the stimulator means or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator means, required to connect the wires extending from the electrodes to the stimulator means. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the 25 necessary electrical connection between the wires extending from the electrodes and the stimulator means.

The stimulator means is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator means is preferably implantable within a recess in the bone behind the ear posterior to 30 the mastoid.

When implanted, the housing preferably contains, in addition to the stimulator means, a receiver means. The receiver means is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that 35 the signals are transmitted transcutaneously through the skin of the implantee.

Signals can preferably travel from the controller means to the receiver means and vice versa. The receiver means can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can
5 comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets
10 mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The
15 speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted stimulator/receiver means using the transmitter and receiver coils. The implanted stimulator/receiver means demodulates the
20 FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and
25 receiver coils are used to provide power via transcutaneous induction to the implanted stimulator/receiver means and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment,
30 the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator means.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a simplified cross-sectional view of one embodiment of an electrode assembly according to the present invention depicted in its implantable orientation;

Fig. 2 is a simplified side elevational view of the electrode assembly of Fig. 1 depicted in an intermediate orientation;

Fig. 3 is a simplified part-sectional, part side elevational view of the electrode assembly depicted in its pre-formed orientation following insertion in the cochlea; and

Fig. 4 is a simplified cross-sectional view of another embodiment of an electrode assembly according to the present invention; and

Figs 5a-5d depict alternative tip structures for the electrode assembly depicted in Fig. 4.

Preferred Mode of Carrying Out the Invention

One embodiment of a cochlear implant electrode assembly according to the present invention is depicted generally as 10 in the drawings.

The depicted electrode assembly 10 has an electrical lead extending back to a stimulator/receiver housing. In considering this invention, it is to be understood that each electrode 12 may have one or more wires (not depicted) electrically connected thereto and extending from each respective electrode 12 back through the lead to the stimulator/receiver.

The assembly 10 comprises an elongate electrode carrier member 11 having a plurality of electrodes 12 mounted thereon. For the purposes of clarity, the electrodes 12 depicted in Fig. 1 are not necessarily shown to scale. A larger number of electrodes than that depicted in Fig. 1 can also be envisaged. The electrodes 12 are not depicted in Figs. 2 and 3 for reasons of clarity.

The depicted elongate member 11 is preformed from a resiliently flexible silicone with memory and is preformed to a curved orientation suitable for insertion in the scala tympani 31 of a patient's cochlea 30. The elongate member 11 has a first end 13 that is firstly inserted into the cochlea 30 upon insertion of the assembly 10.

As depicted in Fig. 4, the elongate member 11 can have a tip member 29, having a different construction to that depicted in Fig. 1, which is integrally formed with its first end 13. The tip 29 is formed from the same silicone used to fabricate the elongate member 11 and, in the depicted

embodiment, the material of tip member 29 has a resilient flexibility equal to that of the material used for the carrier member 11.

Possible alternative constructions for the tip member 29 are provided in Figs. 5a-5d. As depicted in Fig. 5a, the tip member 70 can be solid and
5 formed of an inner core 71 of relatively stiff material 71 and an outer layer 72 of relatively flexible material. The core 71 can taper in diameter over region 73 towards the distal end 21. The taper 73 causes the overall stiffness of the tip 70 to increase over the length of the taper 73 away from the distal end 21. The outer layer 72 can be formed of the same material as the remainder of the
10 body of the elongate carrier member 11 or can be a different material.

As depicted in Fig. 5b, the tip member 40 can comprise a solid mass integrally formed to the first end 13 of the elongate carrier 11.

Still further and as depicted in Fig. 5c, the tip member 50 can comprise a solid mass 51 that is formed separately from the carrier member 11 and
15 subsequently adhered thereto.

As depicted in Fig. 5d, the tip member 60 can comprise an elastomeric silicone material having a plurality of substantially spherical platinum particles 61 dispersed therethrough. The particles 61 have a diameter between about 50µm and 100µm. It will be appreciated that the particles 61
20 depicted in Fig. 6d are not drawn to scale.

In Fig. 5d, the particles 61 are depicted as substantially evenly dispersed through the tip member 60. In another embodiment, the particles could be non-evenly dispersed through the tip member. For example, the particles could increase in density away from the distal end 21 towards the
25 proximal end of the tip member 60. By varying the density of the platinum particles 61, it is possible to vary the relative stiffness of the tip member 60.

In addition to, or instead of, being used to potentially modify the physical characteristics of the tip member, the provision of the metallic particles 61 also result in the tip member 60 being detectable by fluoroscopy
30 and X-ray techniques. This provides another means for the surgeon to either monitor the placement and position of the tip member 60 during or after insertion of the electrode array 10 in an implantee's cochlea.

Disposed within a lumen 14 is a nickel/titanium (Nitinol™) wire 15. In the depicted embodiment, the wire 15 alone has a stiffness that is sufficient to
35 retain the silicone elongate member 11 in a straight orientation when the wire 15 is at room temperature (as shown in Fig. 1).

Whilst a substantially cylindrical lumen is depicted, the lumen 14 could indeed be any shape necessary to perform the function. The wire 15 has a circular cross-section. Other shape elements having different cross sections and forms can be envisaged.

- 5 As depicted in Fig. 2, the wire has a preferred direction of curl on exposure to body temperature within the cochlea. In one embodiment, the array 10 can have an indicia means that provides an indication to a user, such as a surgeon, of the preferred direction of curl of the array on implantation. This is important as the array 10 needs to be oriented in the
10 cochlea such that the direction of curl results in the array 10 being able to be moved into the scala tympani 31. The indicia means can comprise a loop formed in the wire at or adjacent a distal end thereof. The loop as well as acting as an indicia means can act as a means of engaging with and withdrawing the wire 15 from the lumen 14 during or following implantation.
15 In one embodiment, the loop can be in the same plane as the preferred direction of curl of the wire 15. The loop could extend away from the preferred direction of curl of the wire 15.

- In the embodiment shown in Figure 1, overlaying the depicted elongate member 11 it is possible to provide a sheath 16 of bioresorbable and
20 lubricious material. The bioresorbable material of the depicted stiffening sheath is PAA that is adapted to dissolve on exposure to cochlear fluids. Other suitable bioresorbable materials can be envisaged and such materials need not necessarily dissolve on exposure to fluids. For example, the sheath can be made of a material that softens upon exposure to fluids but does not
25 get absorbed.

While the elongate member 11 is manufactured with a preformed curved orientation, the assembly 10 is typically delivered to a surgeon with the Nitinol wire 15 in place. The wire 15, while at room temperature, holds the elongate member 11 in the straight orientation depicted in Fig. 1.

- 30 Upon insertion into the scala tympani 31 of the cochlea 30, the exposure of the assembly 10 to body temperature (about 37°C) results in the Nitinol wire 15 adopting a curved orientation. As the wire 15 adopts the curved orientation, the elongate member 11 is free to also adopt the curved orientation as is depicted in Fig. 2.

- 35 As the elongate member 11 curls, the surgeon can continue to further insert the assembly 10 into the scala tympani 31. During the further insertion

process, the surgeon can commence withdrawal of the wire 15 through opening 17 of the lumen 14 at end 18. Alternatively, the surgeon may withdraw the wire 15 following complete insertion of the assembly into its final position, this decision being dependent of the surgeon's preferences.

5 Upon withdrawal of the wire 15, the elongate member 11 is free to adopt its pre-formed spiral orientation (as is depicted in Fig. 3), with the electrodes facing the modiola within the cochlea 30 so that they are positioned as close as possible to the spiral ganglia thereof.

The provision of the shape memory wire 15 provides the surgeon with greater control of the implantation procedure for the cochlear implant electrode assembly 10. The provision of greater control minimises the potential for trauma to the sensitive tissues inside the cochlea and also enhances the likelihood of successful placement of the assembly 10 at the first attempt.

15 While the preferred embodiment of the invention has been described in conjunction with a cochlear implant, it is to be understood that the present invention has wider application to other implantable electrodes, such as electrodes used with pacemakers.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

20

CLAIMS:

1. An implantable tissue-stimulating device comprising:
a stimulating means;
an elongate member coupled to said stimulating means made of a
5 resiliently flexible first material and having a length and a plurality of
electrodes mounted thereon adapted to apply a preselected tissue stimulation,
the elongate member having a pre-formed orientation, an implantable
orientation different to said pre-formed orientation that allows said member
to be inserted into an implantee's body, and an at least one intermediate
10 orientation between said implantable and said pre-formed orientation; and
a shape element removably positioned within the elongate member and
extending along at least a portion of the length thereof, said element having:
a first shape selected for biasing said elongate member into said
implantable orientation when the shape element is at a first temperature; and
15 at least a second shape that allows the elongate member to adopt
said at least one intermediate orientation when the shape element is exposed
to a pre-determined temperature different than said first temperature.
2. A cochlear implant electrode assembly device comprising:
20 an elongate electrode carrier member made of a resiliently flexible first
material and having a length and a plurality of electrodes mounted thereon
adapted to apply a preselected tissue stimulation, the elongate member
having a pre-formed curved orientation that at least substantially matches an
inside surface of a cochlea, an implantable orientation different to said pre-
25 formed orientation that allows said member to be inserted into an implantee's
cochlea, and an at least one intermediate orientation between said
implantable orientation and said pre-formed orientation; and
a shape element removably positioned within the elongate member and
extending along at least a portion of the length thereof, said element having:
30 a first shape selected for biasing said elongate member into said
implantable orientation when the shape element is at a first temperature; and
at least a second shape that allows the elongate member to adopt
said at least one intermediate orientation when the shape element is exposed
to a temperature of the cochlea being different than said first temperature.

3. A device of claim 1 wherein the pre-formed orientation of the elongate member is curved.
4. A device of claim 3 wherein the elongate member adopts a spiral
5 curvature when in the pre-formed orientation.
5. A device of claim 1 or claim 2 wherein the shape element is formed from a shape memory material that is relatively stiffer than the first material.
- 10 6. A device of claim 5 wherein the shape memory material is a metal or metal alloy, and the shape element biases the elongate member of the electrode array in at least a substantially straight orientation while the array is at a temperature different to human body temperature.
- 15 7. A device of claim 5 wherein the shape memory material is a plastics material.
8. A device of claim 6 wherein the shape memory material is Nitinol™.
- 20 9. A device of claim 6 wherein on insertion into the body and exposure to body temperature, the shape element adopts at least the second shape.
10. A device of claim 9 wherein upon removal of the shape element the elongate member of the electrode array adopts the implantable orientation.
- 25 11. A device of claim 10 wherein upon removal of the shape element the elongate electrode carrier member adopts its pre-formed curved orientation that at least substantially matches an inside surface of a cochlea.
- 30 12. A device of claim 2 wherein the elongate member is preformed from a biocompatible plastics material and has a first end that is firstly insertable into the implantee.
- 35 13. A device of claim 12 wherein the elongate member is formed from a biocompatible material selected from the group comprising a silicone, and a polyurethane.

14. A device of claim 12 wherein the shape element is removably positionable within a lumen extending through the elongate member for at least a portion of its length.
- 5 15. A device of claim 14 wherein the lumen extends through the elongate member for a substantial portion of its length from an opening distal the first end to or adjacent the first end.
- 10 16. A device of claim 15 wherein the shape element extends out of the opening allowing the element to be manipulated and removed from the lumen during insertion of the device.
- 15 17. A device of claim 2 wherein the plurality of electrodes are mounted along a surface of the elongated member that at least substantially conforms to the inside surface of the cochlea.
18. A device of claim 1 or claim 2 wherein the elongate member has an outer layer that acts as a stiffening sheath for the elongate member.
- 20 19. A device of claim 18 wherein the stiffening sheath is formed of a bioresorbable material which dissolves or softens on exposure to a fluid.
20. A device of claim 19 wherein the bioresorbable material of the stiffening sheath is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).
- 25 21. A device of claim 18 wherein the device has an additional layer surrounding the stiffening sheath, the additional layer having a first rate of fluid ingress therethrough and having at least one fluid ingress means formed therein, the rate of fluid ingress through the fluid ingress means being greater than the first rate of fluid ingress through the additional layer.
- 30 22. A device of claim 21 wherein the fluid ingress means comprise one or more openings in the additional layer.
- 35

23. A device of claim 1 or claim 2 wherein at least a portion of an outer surface of the elongate member can has a coating of a lubricious material.
- 5 24. A device of claim 23 wherein the lubricious material is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).
- 10 25. A device of claim 12 wherein a resiliently flexible tip member extends forwardly from the first end of the elongate member.
26. A device of claim 25 wherein the tip member has a plurality of metallic particles dispersed therethrough.

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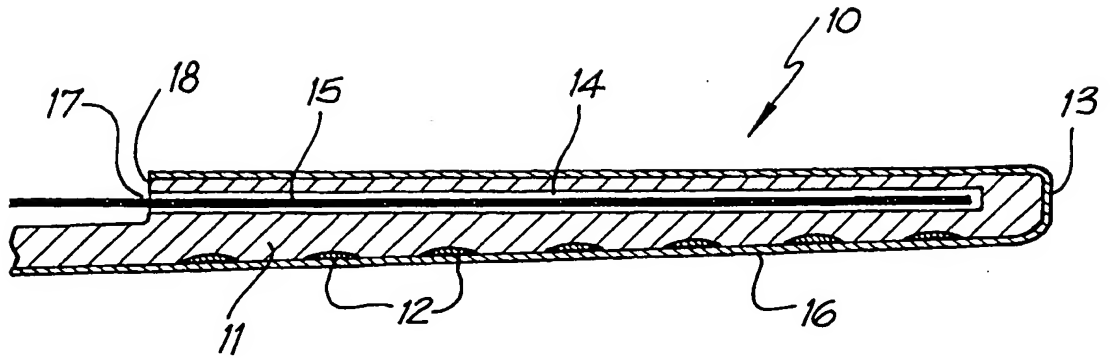


FIG. 1

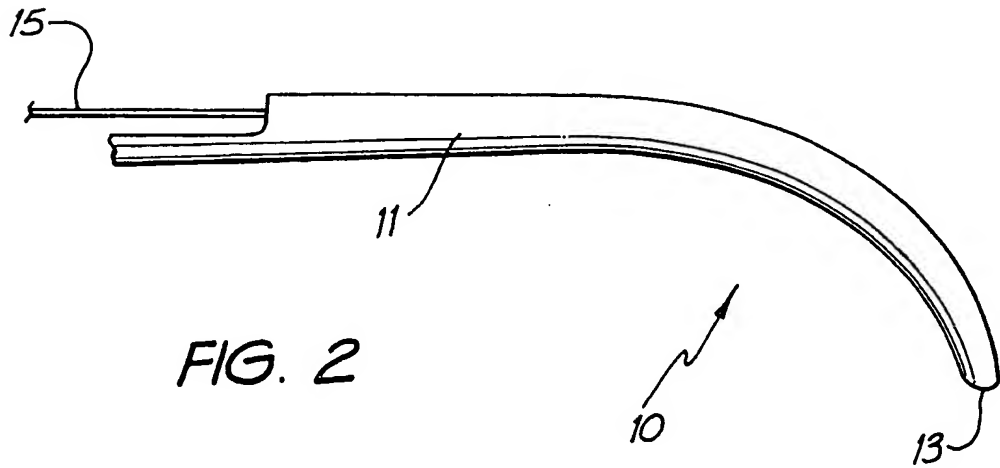


FIG. 2

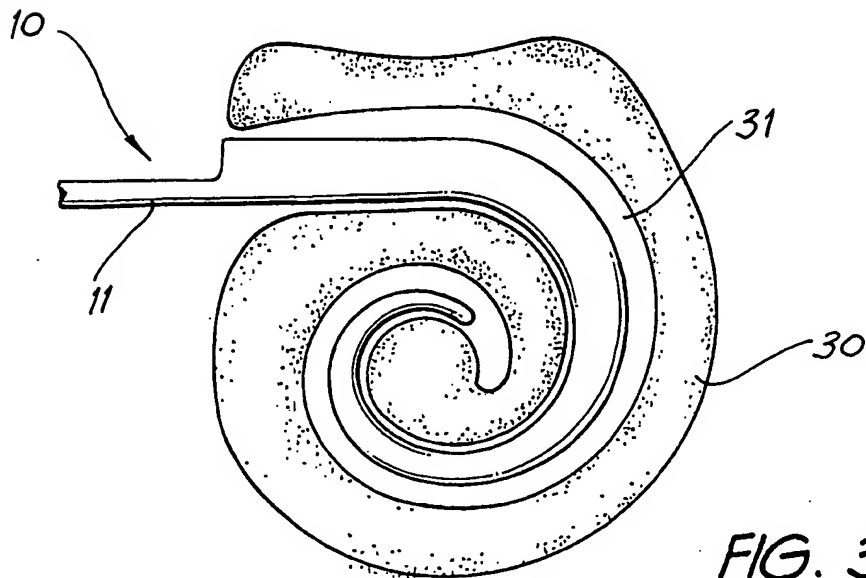


FIG. 3

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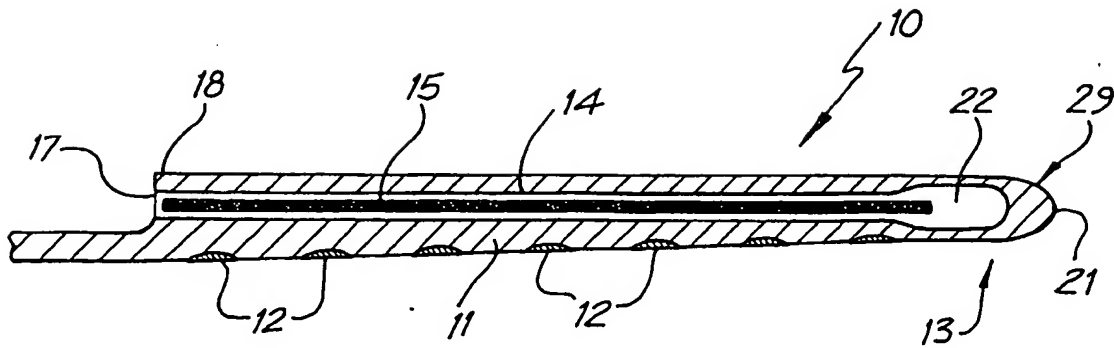


FIG. 4

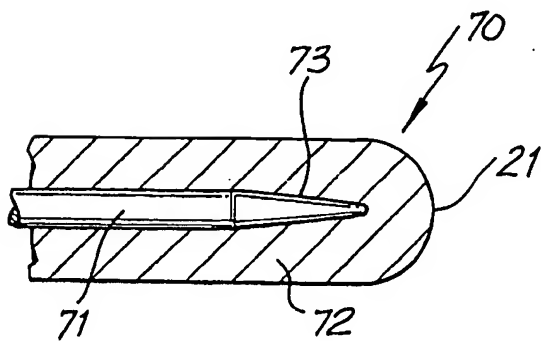


FIG. 5a

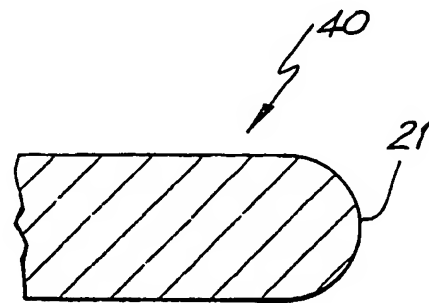


FIG. 5b

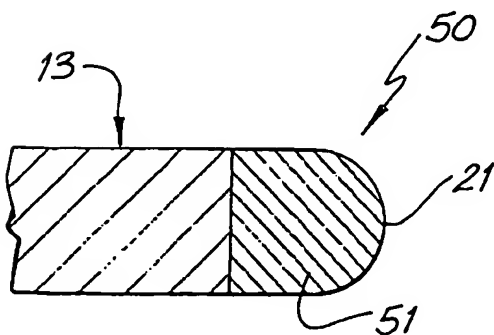


FIG. 5c

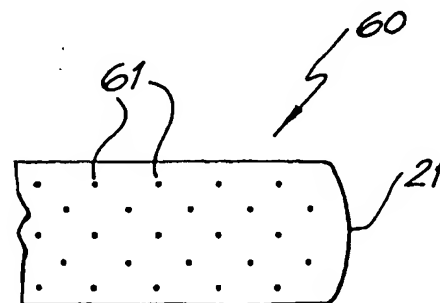



FIG. 5d

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/01312

A. CLASSIFICATION OF SUBJECT MATTER																						
Int. Cl. ⁷ : A61N 1/05, A61F 11/04																						
According to International Patent Classification (IPC) or to both national classification and IPC																						
B. FIELDS SEARCHED																						
Minimum documentation searched (classification system followed by classification symbols) REFER ELECTRONIC DATABASE CONSULTED BELOW																						
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched																						
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI: & keywords: electrode, implant, stylet, memory shape and similar terms.																						
C. DOCUMENTS CONSIDERED TO BE RELEVANT																						
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																				
A	US 6119044 A (KUZMA) 12 September 2000 See column 8 lines 1-15, column 15 line 47-column 16 line 57.																					
A	US 3890977 A (WILSON) 24 June 1975 See column 1 line 44-column 2 line 4, column 3 lines 1-41.																					
A	GB 2217993 A (MIROWSKI) 8 November 1989 See page 14 line 15-page 16 line 19.																					
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex																						
<p>* Special categories of cited documents:</p> <table border="0"> <tr> <td>"A"</td> <td>document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T"</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E"</td> <td>earlier application or patent but published on or after the international filing date</td> <td>"X"</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L"</td> <td>document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y"</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O"</td> <td>document referring to an oral disclosure, use, exhibition or other means</td> <td>"&"</td> <td>document member of the same patent family</td> </tr> <tr> <td>"P"</td> <td>document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table>			"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family	"P"	document published prior to the international filing date but later than the priority date claimed		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention																			
"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone																			
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art																			
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family																			
"P"	document published prior to the international filing date but later than the priority date claimed																					
Date of the actual completion of the international search 10 December 2001		Date of mailing of the international search report 19 DEC 2001																				
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929		Authorized officer  JOHN HO Telephone No : (02) 6283 2329																				

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/01312

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5762630 A (BLEY et al.) 9 June 1998 See entire document.	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU01/01312

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	6119044	AU	92074/98	EP	1009475	US	6038484
		US	6045993	US	6078841	US	6129753
		US	6144883	WO	9911321	US	6149657
		US	6163729	US	6195586	US	6304787
		US	6309410	US	6321125	AU	64049/99
		EP	1159027	WO	200047272	US	6266568
		US	6125302	US	6070105	AU	43168/99
		EP	1082466	WO	9963118	US	6228577
		AU	200046550	WO	200064529	AU	200048460
		US	6259951	WO	200069513	AU	200047129
		WO	200069512				
US	3890977	FR	2262536	GB	1499520	JP	50141187
GB	2217993	CA	1334030	DE	3912377	FR	2630013
		JP	2063478	NL	8900925	US	5052407
		AU	33729/89	BE	1004208		
US	5762630	AU	49211/97	CA	2225442	EP	850657
		JP	10216237				
END OF ANNEX							